

Patients with stage IB1 & positive nodes, IB2, II, IIIB or IVA cervical cancer who have given informed consent

Eligible patients

RANDOMISE

Max 6 weeks

Arm A – Control Arm
Concurrent chemoradiation

Arm B – Intervention Arm
Concurrent chemoradiation
followed by adjuvant
chemotherapy

Follow up for a minimum of 3 years

ANZGOG 2015

ANNUAL SCIENTIFIC MEETING

25-28 March 2015 | Sofitel Broadbeach

Celebrating 15 years of research

OUTBACK Trial

A/Prof Linda Mileskin



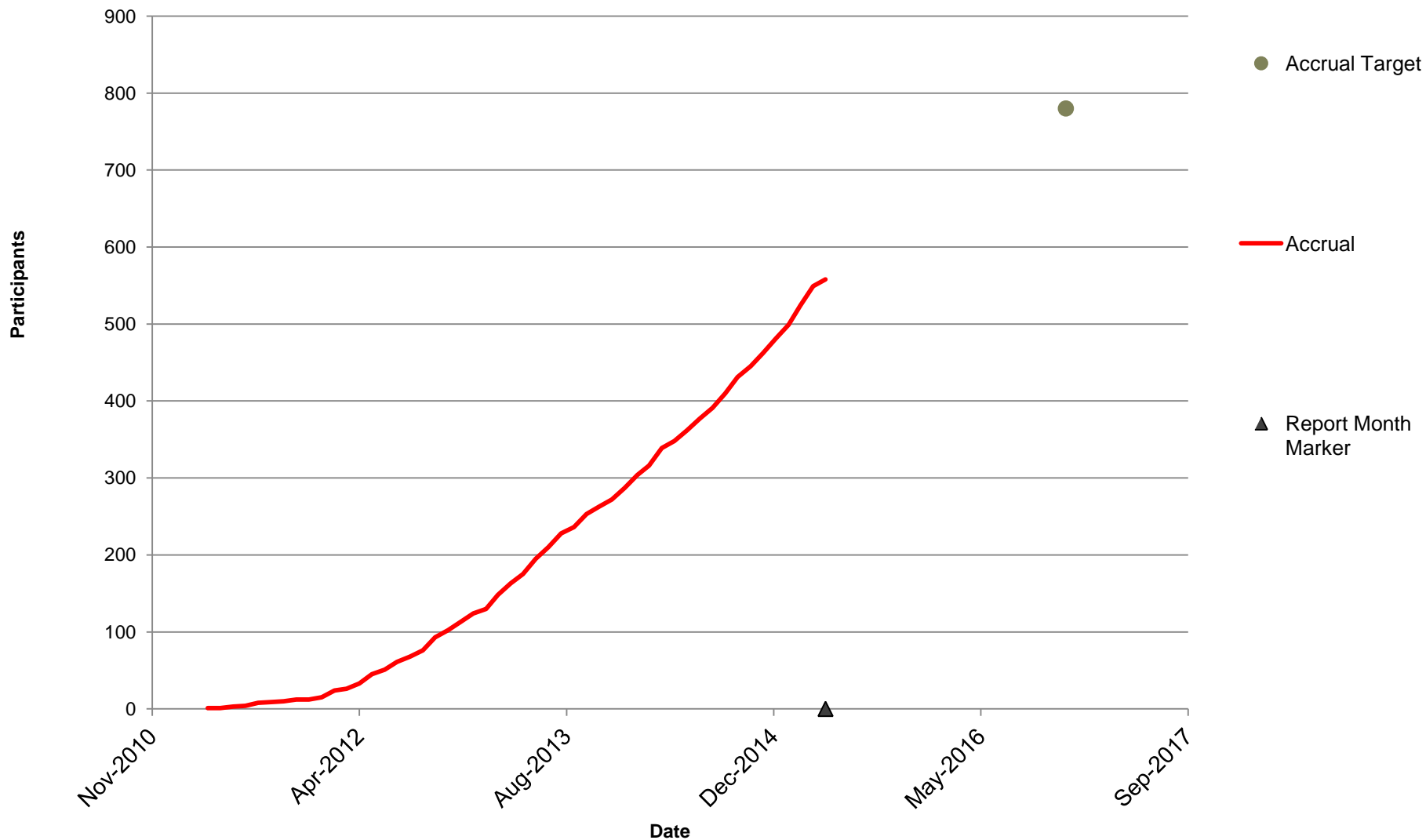
AUSTRALIA NEW ZEALAND
GYNAECOLOGICAL ONCOLOGY GROUP

Trial Status

- 248 sites open (16 ANZGOG, 232 NRG Oncology)
- Sites in Australia, NZ, USA, Canada, Saudi Arabia & Singapore
- Trial to possibly open in Columbia & Brazil
- 558 patients recruited (120 ANZGOG, 438 NRG Oncology)
- Accrual target is 780 patients

Accrual graph

Accrual



Serious Adverse Events

- 198 SAEs have been reported
 - No SUSARs

Treatment Phase	SAEs	Related	Unrelated
Chemoradiation	161	94	67
Adjuvant chemotherapy	37	24	13

- Event rate too low to perform initial futility analysis yet
- Ongoing efforts to improve submission of cases for radiotherapy QA
- Ongoing work to activate sites in
 - China
 - Brazil and Columbia
 - ?? India as law re insurance and sponsorship is changing